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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,848	06/18/2001	Leona E. Ling	CIBT-P01-119	9957
28120	7590	07/15/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/883,848

## Applicant(s)

LING ET AL.

## Examiner

Brandon J Fetterolf, PhD

## Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 3-24 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1642

Lin *et al.*

Priority date : 6/18/2001

### DETAILED ACTION

The response filed on May 10, 2004 to the restriction requirement of April 7, 2004 has been received. Applicant's election with traverse of Group II, claims 1-2, 25-27 and the structure presented in Exhibit 1 is acknowledged. The traversal is on the ground(s) that the invention of Group I, claims 1-17, and the invention of Group II, claims 1-2 and 25-27, encompass overlapping subject matter based on methods of promoting angiogenesis and therefore, could be examined simultaneously without significant additional burden. This is not found persuasive because Group I, claims 1-17 are specifically drawn to a method of promoting angiogenesis comprising the administration of an angiogenic peptide, wherein the peptide could be any amino acid sequence set forth in SEQ ID NOs: 1-20 or 26. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search for twenty-one different polypeptides, and different polypeptide segments in the databases, in addition to searching the organic molecule databases would require extensive searching and review.

The requirement is still deemed proper and is therefore made FINAL.

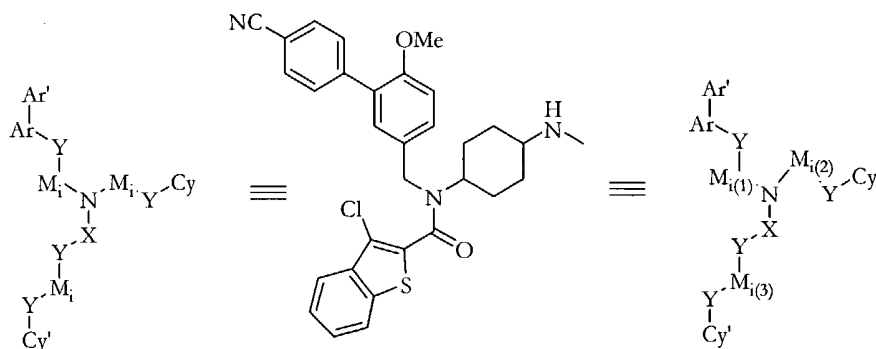
Claims 1-34 are currently pending in the application.

Claims 3-24 and 28-34 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-2 and 25-27 in respect to the structure presented in Exhibit 1 are currently under consideration.

Note: Listed below is the examiners interpretation of Exhibit 1 provided and elected by the applicant as the agonist for consideration.

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Formula (XII)  
(Spec, page 71)

Exhibit 1  
Election 5/10/2004

Examiners interpretation of Exhibit I relative to Formula XII

Y= absent

$M_{i(1)} = \text{CH}_2$

Ar'= substituted cyano aromatic

Ar=substituted  $-\text{O}(\text{CH}_2)_n\text{R}$  aromatic

$M_{i(2,3)} = \text{absent}$

Cy- aminosubstituted nonaromatic ring

X=  $-\text{C}=\text{O}$

Cy'= substituted benzothiophene

### Priority

A review of the provisional application serial number 60/211,919 did not lend support for the disclosure of a small organic molecule represented by the general formula (XII) as a hedgehog agonist. If applicant disagrees with any rejection of claims 1-2 and 25-27 set forth in this office action based on examiner's establishment of a priority date of **June 18, 2001** for the instant claims in application serial number 09/883,848 applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

### Claim Objections

Claims 1-2 are objected to because of the following informalities: Claims 1-2 refers to a hedgehog polypeptide which was non-elected subject matter. Appropriate correction is required.

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*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Porter et al. (US Patent 6,613,798, 3/30/2000).

Porter et al teaches methods of administering the patentably disclosed agonistic of interest, Exhibit 1 (Agonist D in Patent, Figure 32A-1) to animals for the purpose of activating the hedgehog pathway (column 18, lines 40+). This includes the treatment or prevention of a variety of damaged epithelial and mucosal tissues, for instance to control wound healing (column 20, lines 31+). Inherently, the administration of such agonists would promote angiogenesis. The patent office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Therefore, NO claim is allowed.

The examiner of the application has changed. This case has now been transferred as of July 9, 2004. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Brandon Fetterolf PhD, Group Art Unit 1642.

Art Unit: 1642

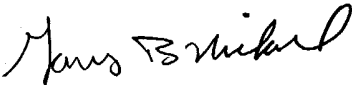
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF

  
**GARY B. NICKOL, PH.D.**  
**PRIMARY EXAMINER**